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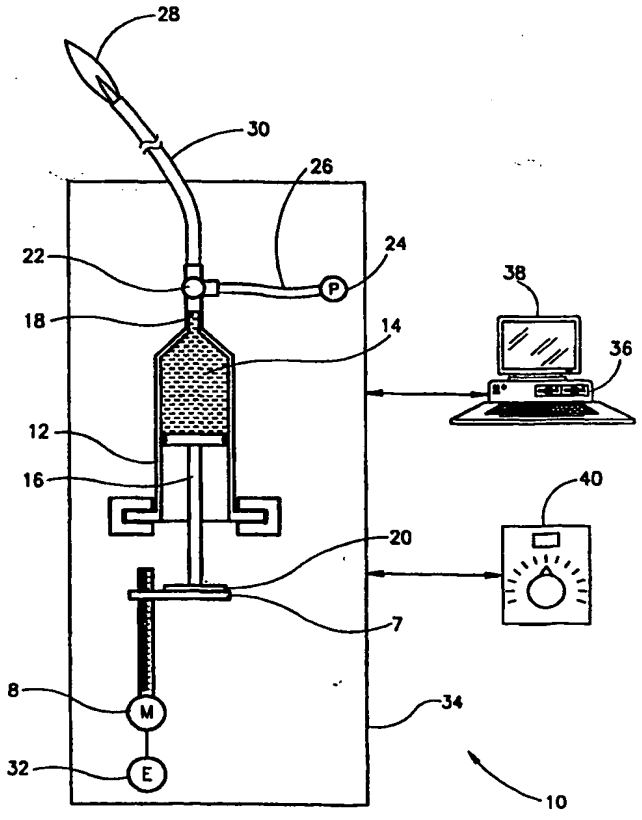
(54) Title: ANGIOPLASTY PRESSURE/VOLUME CONTROL SYSTEM

(57) Abstract

A method and apparatus for monitoring the pressure and volume of a balloon which is inflated by a pressurized liquid in order to perform the medical procedure of angioplasty. This method and apparatus provides detailed pressure vs. volume information during the procedure. Better control during and analysis of results after the procedure are thereby achieved.



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ANGIOPLASTY PRESSURE/VOLUME CONTROL SYSTEM

FIELD OF THE INVENTION

The present invention relates to apparatus used with balloon catheters in angioplasty procedures.

BACKGROUND OF THE INVENTION

Balloon angioplasty revascularisation and stent implantation are well known medical techniques used to treat coronary and other vascular diseases. These diseases are usually characterized by a constriction in an arterial wall made up of plaque, known as a stenosis. The plaque is either hard or calcified or soft and malleable depending on the nature of the stenosis. The stenosis prevents arterial blood flow and starves an organ supplied by an artery of oxygen. Balloon angioplasty involves inflation of a balloon within the artery in order to ease the constriction by either compressing matter comprising the stenosis towards the arterial wall and/or by stretching the arterial wall and expanding the artery, in accordance with the compressibility of the stenosis. Optionally, a stent may then be implanted which retains the matter comprising the stenosis in the compressed state or maintains the expansion of the artery. Arterial blood flow is thus improved.

The balloon is inserted through an artery until it reaches a stenotic area. The balloon is then inflated by the use of a liquid, usually comprising a saline solution of iodine contrast material. The liquid is fed to the balloon via a lumen in a catheter tube which is connected to a syringe. An operator pushes the syringe by hand or by a hand operated tool and monitors the liquid pressure. The operator monitors the level of inflation of the balloon via an angiogram, fluorograph, ultrasound or other imaging technique. He then determines when to end the procedure, based on the level of inflation of the balloon and/or the pressure reached.

SUMMARY OF THE INVENTION

An object of an aspect of the present invention is to provide a device for applying pressure to a balloon, used to compress a stenosis in an artery and/or to expand an arterial wall at the point of a stenosis in the artery, using a liquid whilst providing a measurement of the volume of the compressed stenosis or the increase in volume of the artery due to expansion of the arterial wall. This object is obtained by measuring the volume of liquid supplied to the balloon. The pressure of the liquid for any given volume of the compressed stenosis is also preferably measured. Thus, the volume of the stenosis which is compressed and/or the expansion of the artery at the point of the stenosis for a given applied pressure may be monitored.

In one aspect of the present invention a curve of pressure against volume of compressed stenosis and/or pressure against volume of expansion of the artery is generated and preferably displayed.

In another aspect of the invention, the relationship between the applied pressure and the volume of the compressed stenosis and/or between the applied pressure and the volume of expansion of the artery is monitored, preferably during one or more of three phases of treatment of the stenosis. These phases include (a) initial inflation, before the balloon begins to substantially compress the stenosis and/or to expand the arterial wall at the point of the stenosis; (b) after the onset of compression of the stenosis and during its compression or after the onset of expansion of the arterial wall and during its expansion; and (c) on re-examination after deflation. The three phases correspond to pre, during and post-treatment phases.

In the pre-treatment phase the operator can be made immediately aware of the time when the balloon begins to compress the stenosis and/or expand the arterial wall by the abrupt increase in the gradient of the applied pressure against volume of stenosis curve at that point. During the treatment the variation of applied pressure with changes in compressed volume of the stenosis may yield details of the structure of the stenosis and of the flexibility, stiffness and volume thereof thus indicating whether the stenosis is made up of hard or calcified matter or soft malleable matter. Knowledge of the composition of the stenosis may determine the limits of the parameters of applied pressure and volume of the balloon permitted during the remainder of the treatment as the expansion of the arterial wall resulting from angioplasty performed on a hard stenosis is far more pronounced than that produced by the treatment of a soft, compressible stenosis. Thus, a patient is at greater risk of injury in the former case and the appropriate limits may be varied. In post-treatment, the effectiveness of the treatment can be evaluated by determining from the curve the extent of re-stenosis, by monitoring the point at which the stenosis begins to be compressed . The difference in volume between the points at which the stenosis begins to be compressed pre and post treatment yields the decrease in volume of the stenosis, due to treatment.

During all the treatment phases the volume of liquid supplied to the balloon can be measured extremely accurately and the level of inflation of the balloon can be determined visually to give the operator maximum control of the inflation of the balloon. The pressure and volume parameters of the balloon when compressing the stenosis and/or the arterial wall and the level of inflation of the balloon, visually, may also be monitored to ensure that the arterial

wall does not exceed its limits in terms of elasticity and strength and that therefore the artery is not ruptured.

There is thus provided, in accordance with a preferred embodiment of the invention, apparatus for inflating a balloon used for widening a narrowed artery at a point where a constriction or stenosis has occurred comprising a source of a pressurized liquid which is supplied to the balloon; and a meter which measures the volume of liquid supplied to the balloon.

Preferably, the source of pressurized liquid comprises a syringe. The displacement of the syringe is, preferably, effected by means of a linear electric motor. Preferably, the linear electric motor is attached to a digital encoder which generates an electric signal proportional to the displacement of the linear electric motor.

A preferred embodiment of the apparatus includes a sensor for sensing the pressure of the liquid supplied to the balloon. The apparatus preferably includes circuitry which monitors the pressure and volume of the liquid supplied to the balloon. Alternatively or additionally, the apparatus preferably includes circuitry which controls the pressure of the liquid supplied to the balloon. Alternatively or additionally, the apparatus preferably includes circuitry which generates a pressure vs. volume curve. Alternatively or additionally, the apparatus preferably includes circuitry which ascertains the rate of change of pressure with volume.

The apparatus preferably includes circuitry which ascertains a gradient shift point and outputs the pressure and volume values at that point. Preferably, the apparatus includes circuitry which calculates an increase in volume of the artery at the stenosis by subtracting the volume values at the gradient shift point acquired by the apparatus before and after treatment.

In a preferred embodiment of the invention the liquid supplied to the balloon preferably comprises a saline solution. Preferably, the saline solution comprises iodine.

There is further provided apparatus for widening a narrowed artery comprising a balloon and apparatus for inflating the balloon as described above.

There is further provided, in accordance with a preferred embodiment of the invention, a method of monitoring the volume of an increase in the lumen of an artery during angioplasty using an inflated balloon, the method comprising placing the balloon at a stenosis; inflating the balloon by supplying it with a liquid; measuring the volume of the liquid supplied to the balloon during compression of the stenosis; and monitoring the volume of the compressed stenosis from the measured liquid volume. Preferably, a pressure of the liquid of the balloon is measured during its inflation. Preferably, measuring includes identifying a first point where the

rate of increase of pressure with volume increases during a treatment phase. Preferably, measuring includes identifying a second point where the rate of increase of pressure with volume increases during a post-treatment phase. Preferably, the method includes subtracting the volume corresponding to the first point from the volume corresponding to the second point to yield the increase in volume of the artery at the point of the stenosis. Additionally or alternatively, the method preferably includes representing the pressure and volume as a curve of pressure against volume. Preferably, the method includes displaying the curve of pressure against volume.

Additionally or alternatively, the method preferably includes calculating the rate of change of volume with pressure to yield strength and stiffness characteristics of the stenosis. Preferably, the method includes selecting a limit of the value of the pressure of the liquid in accordance with the characteristics of the stenosis. The method preferably includes evacuating the liquid when the limit of the value of the pressure of the liquid is reached. Additionally or alternatively, the method preferably includes selecting a limit of the value of the volume of the liquid in accordance with the characteristics of the stenosis. The method preferably includes evacuating the liquid when the limit of the value of the volume of the liquid is reached.

The invention will be more clearly understood by reference to the following description of preferred embodiments thereof in conjunction with the figures in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a partially sectional schematic illustration of a device for applying pressure to a balloon via a syringe using a liquid whilst providing detailed data of pressure against volume of the balloon, according to a preferred embodiment of the present invention;

Figs. 2A-2C are schematic illustrations of a balloon when employed in pre (Fig. 2A), during (Fig. 2B) and post (Fig. 2C) - treatment phases of angioplasty, in accordance with a preferred embodiment of the present invention; and

Fig. 3 illustrates typical pressure vs. volume curves obtained, in accordance with a preferred embodiment of the present invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

An object of an aspect of the present invention is to provide a system and method for the application of the technique of angioplasty, to widen an artery at the point where a stenosis or blockage occurs, which yields detailed real-time pressure vs. volume information.

Referring now to the drawings, Fig.1 illustrates a configuration of a control system 10, according to a preferred embodiment of the present invention.

Control system 10 comprises a syringe 12 filled with a liquid 14. Syringe 12 incorporates a piston 16 used to eject solution 14 from an outlet 18 of syringe 12. At an end of the piston opposite exit 18 a flat area 20 is preferably formed and a moveable pushing/pulling plate 7 is attached to and pushes against flat area 20 to move piston 16 and eject solution 14 from or draw solution 14 into the syringe. A linear motor 8 attached to pushing/pulling plate 7 provides the motive force for moving pushing/pulling plate 7 forwards or backwards.

The system further preferably includes a 3-way stopcock, 22, which is attached to syringe 12 at outlet 18. Stopcock 22 may be used to shut off the flow of liquid. A pressure transducer 24 is attached to one arm of 3-way stopcock 22 via a tube 26. Pressure transducer 24 thus measures the pressure in solution 14. A balloon 28, as is common to the art of angioplasty, is attached to 3-way stopcock 22, via a catheter 30. This arrangement enables solution 14 to be ejected through a lumen in catheter 30 into balloon 28 while monitoring the pressure. Solution 14 may also be drawn back into syringe 12 through the lumen in catheter 30 whilst monitoring the pressure. The range of pressures generally applied to balloon 28 varies from 0-20 ATM.

In a preferred embodiment of the invention, control system 10 further includes a digital encoder 32 attached to motor 8 to provide accurate data concerning the displacement of piston 16. Digital encoder 32 is sensitive enough to detect very small displacements associated with even the smallest balloons used in angioplasty procedures. Knowledge of this displacement and the dimensions of the syringe enables accurate measurement of the volume of solution 14 in balloon 28. Syringe 12, pressure transducer 24, pushing/pulling plate 7, linear motor 8 and digital encoder 32 are preferably mounted on a console 34.

In a preferred embodiment of the present invention, solution 14 consists of a saline solution with iodine so that balloon 28 is visible on an angiogram. Other solutions which are described in the art may also be used. The balloon may be imaged via a fluorograph, ultrasound or other imaging technique as is known in the art.

In a preferred embodiment of the present invention the system further includes a computer 36 having a monitor 38 and a pressure selection console 40. In a further preferred embodiment of the present invention, software is used to analyze the incoming balloon pressure and syringe displacement signals so that they may be displayed on a graph of applied pressure against compressed volume of stenosis and/or volume of artery at site of stenosis on monitor 38. In a further preferred embodiment of the present invention, computer 36 maintains a pressure, for example that selected by an operator on pressure selection console 40, via a feedback loop (not shown) connected to linear motor 8. Computer 36 rapidly reduces the

pressure by activating linear motor 8 in reverse when it detects a large increase in the volume of the balloon, which indicates the onset of plasticity in the artery or, possibly a ruptured artery. The rapid increase in volume is preferably also represented on monitor 38.

The embodiment of the invention as shown in Fig.1 is a preferred embodiment and the components used to achieve monitoring of pressure of balloon 28 and volume of solution 14 supplied may be varied so long as the function of the system is preserved. Syringe 12, linear motor 8, stopcock 22 may consist of any receptacle or reservoir capable of holding quantities of solution 14 and pumping them into balloon 28 via tube 30, whilst monitoring the volume supplied. Thus, a pump with a flow-meter attached may be employed. Likewise, the pressure in solution 14 can be monitored in alternative ways as is known in the art. Also, computer 36 may consist of other suitable circuitry.

Figs. 2A-C show an artery 42 containing a stenosis or constriction 44 before, during and after treatment in accordance with a preferred embodiment of the invention. Fig. 2A illustrates the pre-treatment stage. An operator inserts, with the aid of an angiogram, a deflated balloon 28 with or without a stent (as required medically) into artery 42 until it reaches stenosis 44. The operator then slowly inflates balloon 28 by selecting increasingly higher pressures of solution 14 using pressure selection console 40 as shown on Fig. 1. A curve illustrating the pressure vs. volume injected into the balloon is shown as curve A in Fig. 3 - referred to herein as Fig. 3(A). Until the balloon begins to compress the stenosis little or no pressure is required to increase the volume of liquid injected into the balloon, since the balloon meets no resistance as it is inflated. This is illustrated by the portion of Fig. 3(A) up until point (i). The gradient of pressure vs. volume is low, indicating a characteristic large volume change for a small pressure change.

Fig. 2B illustrates the treatment stage. The operator compresses stenosis 44 or expands arterial wall 46 by further inflating balloon 28 by selecting increasing pressures of solution 14 using console 40. This causes the constriction in artery 42 to be reduced by the pressure of balloon 28 on stenosis 44 which compresses stenosis 44 or expands arterial wall 46. After compression of stenosis 44 or expansion of arterial wall 46 the lumen of artery 42 is increased and blood flow in artery 42 is improved. The portion of Fig. 3(A) between points (i) and (ii) shows the pressure vs. volume curve for the treatment phase. The abrupt change in gradient at point (i) indicates that the resistance due to the commencement of compression of stenosis 44 has changed the pressure-volume relation so that a given increment in pressure produces a much smaller increment in volume of balloon 28 than before. In a preferred embodiment of the

present invention, in an initial stage of the treatment phase, the operator monitors the pressure vs. volume characteristic illustrated as Fig. 3(A) between points (i) and (ii) in order to ascertain the strength, flexibility and stiffness of stenosis 44 which can be used to determine the composition of stenosis 44. A high stiffness or high gradient indicates that stenosis 44 consists of cells with a high stiffness containing a high degree of calcium and a low stiffness or low gradient indicates the presence of flexible cells with a low calcium content which has many voids. In a preferred embodiment of the present invention, computer 36 determines whether the stenosis is hard or calcified or soft and malleable based on the pressure vs. volume characteristic and displays this on monitor 38. If the operator determines that stenosis 44 is made up of hard or calcified matter indicating that stenosis 44 will not be compressed greatly by balloon 28 in order to relieve the blockage, but instead arterial wall 46 will expand, he modifies the treatment to include a suitable factor of safety based on a maximum pressure and/or volume allowable at arterial wall 46 as is known in the art. The maximum allowable pressure may vary from patient to patient according to the pressure vs. volume characteristic of his/her artery and a suitable safety factor must be taken into account. Damage to arterial wall 46 is thus prevented . If stenosis 44 is composed of soft, malleable matter, a maximum allowable pressure and/or volume as is known in the art should not be reached in the normal course of the treatment, as the treatment may be terminated when it is determined that arterial wall 46 itself begins to resist.

In a preferred embodiment of the present invention a safety margin is automatically computed by computer 36, after computer 36 displays and analyses the pressure vs. volume characteristic, Fig.3(A) to compute the maximum allowable pressure and volume for the type of stenosis and/or individual patient treated and in a further preferred embodiment of the present invention, computer 36 automatically reduces the pressure and volume of balloon 28 by initiating the removal of a quantity of solution 14 from syringe 12 by activation of linear motor 8 in reverse and hence displacing piston 16 when the maximum allowable pressure and/or volume is reached.

A further increase in gradient at point (ii) indicates that arterial wall 46 itself is resisting the pressure of balloon 28 and/or that stenosis 44 is "fully" compressed so that a given increment in pressure produces an even smaller increment in volume of balloon 28 than before. At this point the operator should stop increasing the volume of balloon 28 in order to prevent rupture of artery 42 if he is treating a soft or malleable stenosis. If the operator is treating a hard or calcified stenosis, further increases in volume of artery 42 may be required to adequately

relieve the blockage, with the computer automatically monitoring the maximum allowable pressure and/or volume. The operator may insert a stent at this stage.

Fig. 2C illustrates the post-treatment phase. During the post-treatment stage balloon 28 is deflated and re-inflated to the point where balloon 28 begins to compress stenosis 44 to obtain the post-treatment volume of stenosis 44 and thus ascertain whether any re-stenosis has occurred where B on Fig. 3 (Fig. 3(B)) shows the pressure vs. volume for the post-treatment phase. The abrupt change in gradient at point (iii) due to the commencement of compression of stenosis 44 indicates the new size of stenosis 44. The higher gradient after this point, indicating a high resistance, shows that artery 42 is almost immediately engaged, indicating successful treatment. A further increase in gradient at point (iv) indicates that arterial wall 46 itself is resisting the pressure of balloon 28. At this point the operator should stop increasing the volume of balloon 28 in order to prevent rupture of artery 42.

The distance between points (i) and (ii) on the x-axis of Figure 3 indicates the decrease in the volume of stenosis 44 as a result of the procedure and/or the increase in the volume of artery 42 at the point of stenosis 44. The operator determines whether the procedure has been successful by comparing the pre and post treatment stenosis volume to decide whether the obstruction to blood flow has been sufficiently decreased. As illustrated on Fig. 3 the volume at point (iii) is almost the same as that at point (ii). This means that little or no re-stenosis has occurred. If point (iii) is at a smaller volume than point (ii) it means that some re-stenosis has occurred. If point (iii) is at a greater volume than point (ii) this may indicate the presence of an aneurysm. In a preferred embodiment of the present invention, computer 36 processes the pressure vs. volume information obtained during and post-treatment by comparing it with previous data to indicate whether the procedure has been successful. The data so obtained is displayed on monitor 38.

An angiograph or other method of visualization of balloon 28, as is common in the art, serves as a rough visual guide for the operator during the procedure and helps to avoid rupture of artery 42.

Variations of the above described preferred embodiments will occur to persons of the art. The above detailed description is provided by way of example and is not meant to limit the scope of the invention which is limited only by the following claims.

WHAT IS CLAIMED IS:

1. Apparatus for inflating a balloon used for widening a narrowed artery at a point where a constriction or stenosis has occurred comprising :

a source of pressurized liquid which is supplied to the balloon; and

a meter which measures the volume of liquid supplied to the balloon.

2. Apparatus according to claim 1 wherein the source of pressurized liquid is a syringe.

3. Apparatus according to claim 2 wherein the displacement of the syringe is effected by means of a linear electric motor.

4. Apparatus according to claim 3 wherein the linear electric motor is attached to a digital encoder which generates an electric signal proportional to the displacement of the linear electric motor.

5. Apparatus according to any of the preceding claims and including a sensor for sensing the pressure of the liquid supplied to the balloon.

6. Apparatus according to claim 5 and including circuitry which monitors the pressure and volume of the liquid supplied to the balloon.

7. Apparatus according to claim 5 or claim 6 and including circuitry which controls the pressure of the liquid supplied to the balloon.

8. Apparatus according to any of claims 5-7 and including circuitry which generates a pressure vs. volume curve.

9. Apparatus according to any of claims 5-8 and including circuitry which ascertains the rate of change of pressure with volume.

10. Apparatus according to claim 9 and including circuitry which ascertains a gradient shift point and outputs the pressure and volume values at that point.

11. Apparatus according to claim 10 and including circuitry which calculates an increase in volume of the artery at the stenosis by subtracting the volume values at the gradient shift point acquired by the apparatus before and after treatment.

12. Apparatus according to any of the preceding claims wherein the liquid supplied to the balloon comprises a saline solution.

13. Apparatus according to claim 12 wherein the saline solution comprises iodine.

14. Apparatus for widening a narrowed artery comprising a balloon and apparatus according to any of claims 1-13.

15. A method of monitoring the volume of an increase in the lumen of an artery during angioplasty using an inflated balloon, the method comprising:

placing the balloon at a stenosis;

inflating the balloon by supplying it with a liquid;

measuring the volume of the liquid supplied to the balloon during compression of the stenosis; and

monitoring the volume of the compressed stenosis utilizing the measured liquid volume.

16. A method according to claim 15 wherein a pressure of the liquid of the balloon is measured during its inflation.

17. A method according to claim 16, wherein measuring includes identifying a first point where the rate of increase of pressure with volume increases during a treatment phase.

18. A method according to claim 17, wherein measuring includes identifying a second point where the rate of increase of pressure with volume increases during a post-treatment phase.

19. A method according to claim 18 and including subtracting the volume corresponding to the first point from the volume corresponding to the second point to yield the increase in volume of the artery at the point of the stenosis.

20. A method according to any of claims 15-19 and including representing the pressure and volume as a curve of pressure against volume.

21. A method according to claim 20 and including displaying the curve of pressure against volume.

22. A method according to any of the preceding claims and including calculating the rate of change of volume with pressure to yield strength and stiffness characteristics of the stenosis.

23. A method according to claim 22 and including selecting a limit of the value of the pressure of the liquid in accordance with the characteristics of the stenosis.

24. A method according to claim 23 and including evacuating the liquid when the limit of the value of the pressure of the liquid is reached.

25. A method according to any of claims 22-24 and including selecting a limit of the value of the volume of the liquid in accordance with the characteristics of the stenosis.

26. A method according to claim 25 and including evacuating the liquid when the limit of the value of the volume of the liquid is reached.

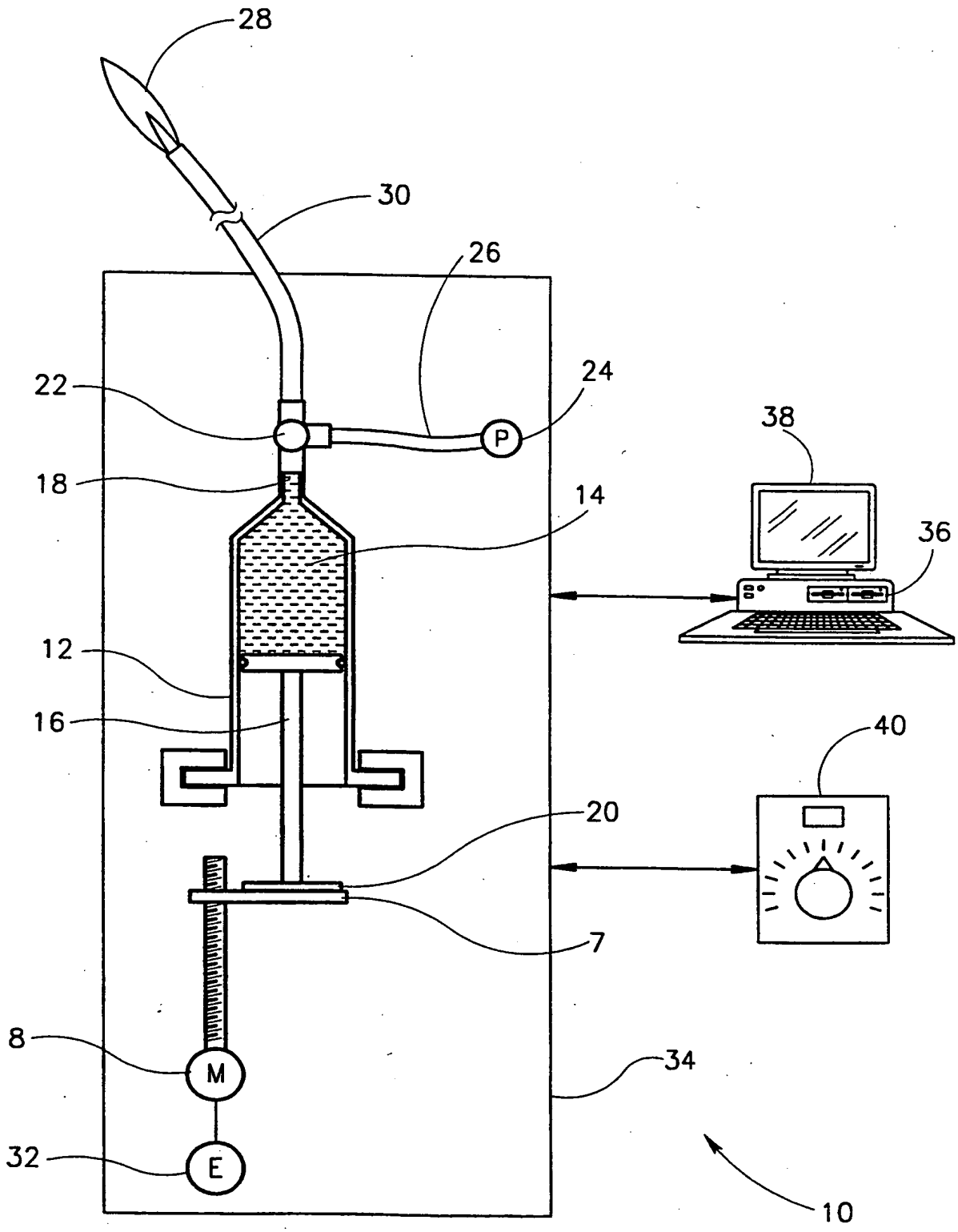

FIG. 1

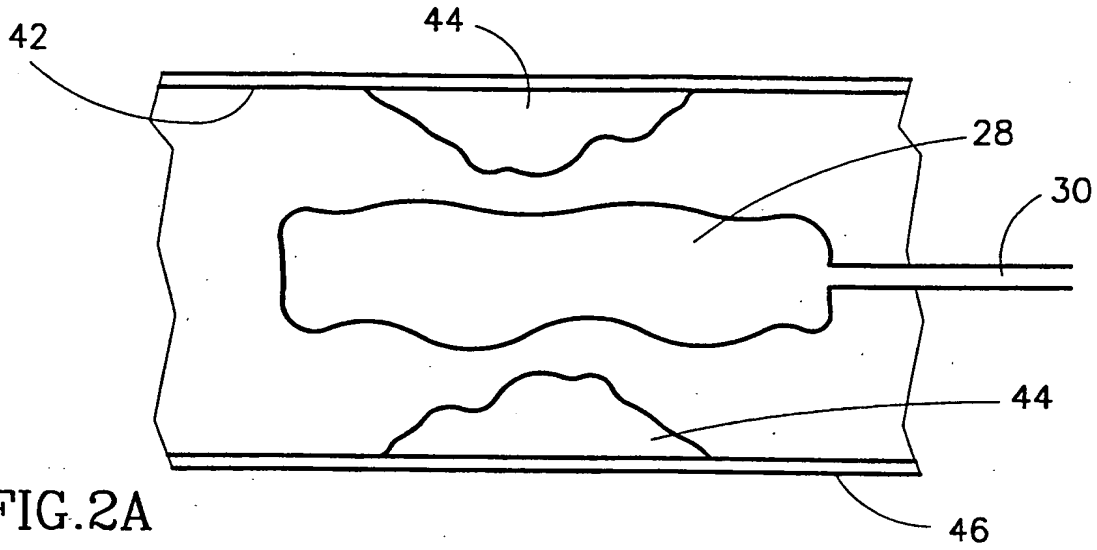

FIG.2A

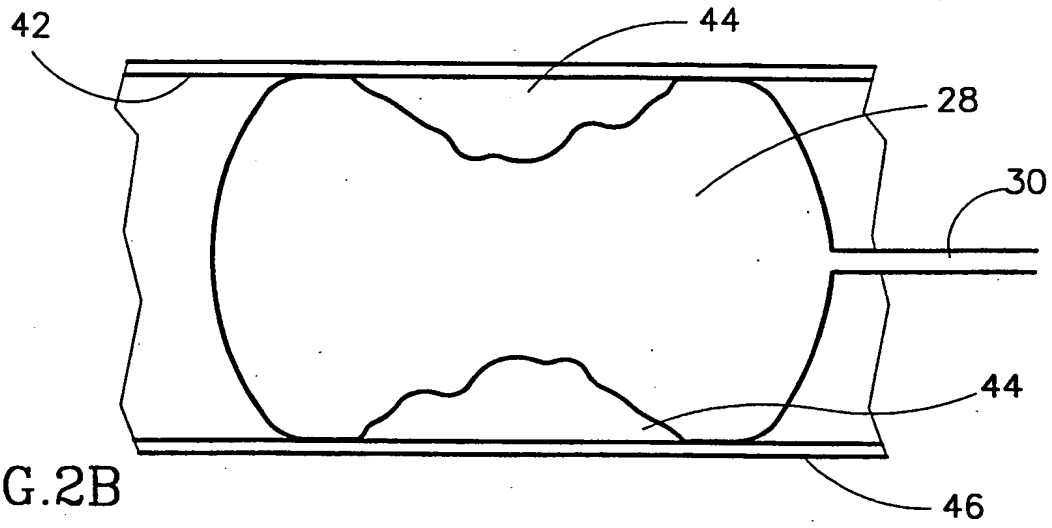

FIG.2B

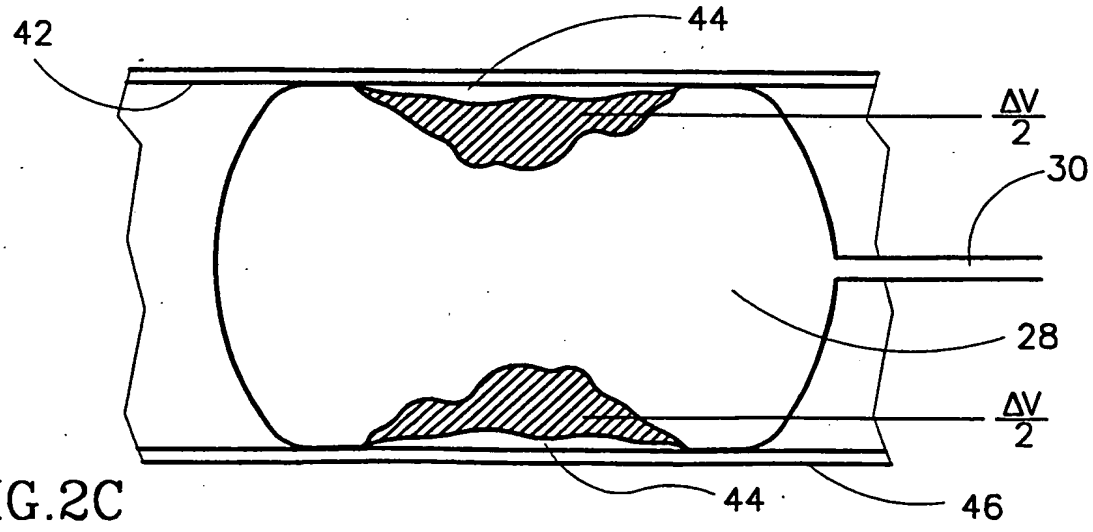

FIG.2C

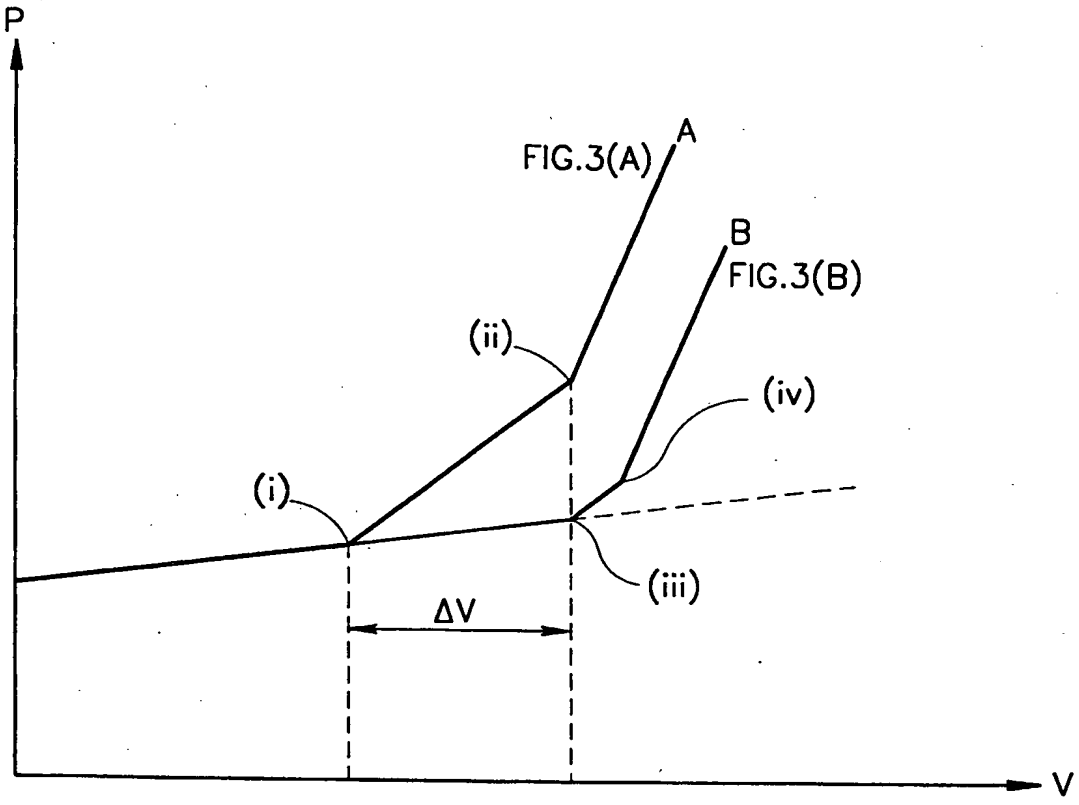

FIG.3

INTERNATIONAL SEARCH REPORT

Intern al Application No
PCT/IL 98/00210

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M25/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 084 060 A (FREUND ET AL.) 28 January 1992 see abstract see column 3, line 8 - line 48 see column 6, line 21 - column 7, line 32; figures 1,4,5A,B --- WO 91 03207 A (BOSTON SCIENT CORP) 21 March 1991 see abstract see page 1, line 29 - page 4, line 32 see page 13, line 20 - page 14, line 54 see page 19, line 28 - page 13, line 6 see page 26, line 15 - column 27, paragraph 15 see page 27, line 31 - line 35; figures 1-4; examples 1,7 --- -/--	1-14 1-14

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
11 September 1998	21/09/1998

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 619 122 A (GETZ BROS CO LTD) 12 October 1994 * The Whole Document *	1-14
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